

As an initial matter, Applicants note that claim 34 has not been rejected by the Office. Accordingly, Applicants request that the Office indicate that the subject matter of claim 34 is allowable in the next Office Action.

## II. Rejections Under 35 U.S.C. § 103

### A. **Wolf in view of Fanchon**

The Office has maintained the rejection of claims 1-23, 27, 28, 33, 35 and 37 under U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,449,519 (Wolf) in view of U.S. Patent No. 5,679,374 (Fanchon) for the reasons set forth at page 2-3 of the outstanding Office Action.

To establish a prima facie case of obviousness, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. See M.P.E.P. 2143.01. The mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination. *Id.*

The Federal Circuit does not take the requirement for motivation lightly, stating that "the best defense against the subtle but powerful attraction of a hindsight-based obviousness analysis is rigorous application of the requirement for a showing of ... motivation. ...The showing must be clear and particular." [emphasis added] See *In re Dembiczak*, 175 F.3d 994, 999 (Fed. Cir. 1999) (abrogated on other grounds).

In more recent cases, the Federal Circuit has held that determinations of prima facie obviousness must be supported by a finding of "substantial evidence". See *In re Zurko*, 258 F.3d 1379, 1386 (Fed. Cir. 2001). Specifically, unless "substantial evidence"

found in the record supports the factual determinations central to the issue of patentability, the rejection is improper and should be withdrawn. See *Zurko*, 258 F.3d at 1386.

On January 18, 2002, the Federal Circuit again reaffirmed the Office's high burden to establish a prima facie case of obviousness. Specifically, the Federal Circuit held that "[t]he factual inquiry whether to combine references must be thorough and searching. It must be based on objective evidence of record. This precedent has been reinforced in myriad decisions, and cannot be dispensed with." *In re Sang-Su Lee*, 277 F.3d 1338, 1343 (Fed. Cir. 2002) (internal quotations and citations omitted). Further, consistent with *Zurko* the Federal Circuit held that "[t]he examiner's conclusory statements ... do not adequately address the issue of a motivation to combine." This factual question is material to patentability, and could not be resolved on subjective belief and unknown authority." *Id.* at 9.

The Wolf/Fanchon combination of the present case lacks the requisite "clear and particular" motivation required to support a prima facie case of obviousness. Instead, the Office merely provides a limitation-by-limitation analysis, pointing out where the references teach the individual limitations, but never provides more than conclusory statements supporting a motive for choosing Applicants' claimed combination. For example, the Office alleges that both Wolf and Fanchon are anti-acne compositions and "[t]hus, the beneficial effect of nanopigments as protective agents in Fanchon ... would be known to one of ordinary skill in the art." See Office Action, p. 2. This statement by the Office is not supported by evidence on the record, as neither Wolf nor Fanchon

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mention any such "beneficial effect" of nanopigments. Such unsupported, conclusory language does not provide the "substantial evidence" necessary to establish motivation.

Further, the Office has entirely failed to provide any evidence to support motivation for choosing the specifically claimed polyamino polymers, and combining them with the nanopigments. As has previously been pointed out on the record, Wolf merely provides a laundry list of possible polymers which may be used as carrier molecules, nearly all of which do not meet Applicants' claim limitations. Further, Wolf fails to teach nanopigments altogether, and merely teaches pigments as an optional ingredient. Accordingly, Wolf fails to provide any suggestion to combine Applicants' specifically claimed polyamino polymers with nanopigments.

Fanchon does not cure the deficiencies of Wolf. Rather, Fanchon only briefly teaches that pigments and nanopigments are known in the art, without providing any suggestion for choosing nanopigments over pigments. Importantly, Fanchon is silent with respect to polyamino polymers of the present invention, and therefore cannot provide the missing motivation to combine nanopigments with Applicants' claimed polyamino polymers.

Thus, the Office has done nothing more than point out where each of the ingredients of Applicants combination are separately taught in the art. The Office's conclusory statement that "the beneficial effect of nanopigments as protective agents in Fanchon ... would be known to one of ordinary skill in the art" (Office Action, p. 2) does not provide the requisite clear and particular motivation. Thus, no "substantial evidence" found in the record supports the factual determinations central to the issue of patentability in this case, as required by the Federal Circuit in recent cases including

*Zurko* and *In re Sang-Su Lee*. Accordingly, the Office failed to fail to meet the burden for establishing a prima facie case of obviousness, and the rejection should be withdrawn.

Regarding independent claim 37, directed to an antioxidant composition, there again is no evidence on the record which would support the Office's rejection. Claim 37 recites, *inter alia*, "[a]n antioxidant composition comprising at least one polyamino polymer ... wherein said polyamino polymer is present in an amount effective to inhibit light-induced peroxidation of proteins, protein derivatives, and lipids." As discussed above, Wolf merely provides a laundry list of possible polymers which may be used as carrier molecules, nearly all of which do not meet Applicants' claim limitations. Wolf does not even mention antioxidants. Therefore Wolf cannot provide the clear and particular motivation necessary to choose Applicants specifically claimed polyamino polymers in an amount effective to inhibit light-induced peroxidation of proteins, protein derivatives, and lipids. Because the necessary "substantial evidence" of motivation has not been provided on the record, no prima facie case of obviousness has been established.

*Final*

**B. Wolf in view of Fanchon and Garrison**

Claims 24-26 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Wolf in view of Fanchon, and further in view of U.S. Patent No. 5,569,651 (Garrison). Applicants respectfully traverse this rejection at least on the grounds that the Wolf in view of Fanchon and Garrison combination fails to teach or suggest Applicants' claimed composition.

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For the reasons set forth above, the Wolf/Fanchon combination fails to teach or suggest Applicants' claimed composition. The Office has applied Garrison in an attempt to teach the chelator EDTA in anti-acne compositions to sequester discoloration-causing metal ions. See outstanding Office Action, p. 3. However, Garrison does not cure the deficiencies of Fanchon because Garrison fails to supply the missing motivation necessary to arrive at Applicants' claimed combination. Applicants therefore respectfully request withdrawal of this rejection.

**III. Conclusion**

Applicant respectfully requests the reconsideration of this application and the timely allowance of the pending claims. Please grant any extensions of time required to enter this response and charge any additional required fees to our Deposit Account No. 06-0916.

Respectfully submitted,

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